

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Allan TANGHOJ et al.

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For: A URINARY CATHETER ASSEMBLY ALLOWING FOR NON-CONTAMINATED INSERTION OF THE CATHETER INTO A URINARY CANAL

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend claims 3-5, 7-9, 11, 12, 14-21, 23, 26-28, 30-32, 34, 37, 38, 40-42, 44, 46-50, 52, 53, 55, 56, 59, 62, 67-70, 72, 76, 77 and 79 as follows:

3. (amended) A catheter assembly according to claim 1, wherein the sealing means is arranged between an outer surface of the urinary catheter and an inner surface of the hose, the cavity thereby defining an upper receptacle located near the proximal end of the package and an oppositely located lower receptacle between the catheter and the hose (for a friction reducing substance).

4. (amended) A catheter assembly according to claim 1, wherein the sealing means comprises a radially outwardly extending protrusion of the outer surface of the catheter.

5. (amended) A catheter assembly according to claim 1, wherein the sealing means comprises at least two radially outwardly extending protrusions of the outer surface of the catheter.

7. (amended) A catheter assembly according to claim 4, wherein at least one protrusion defines a resilient vane adapted to contact an inner surface of the hose.

8. (amended) A catheter assembly according to claim 1, wherein the sealing means comprises at least one radially inwardly extending protrusion of the inner surface of the hose.

9. (amended) A catheter assembly according to claim 1, wherein the sealing means comprises at least two radially inwardly extending protrusions of an inner surface of the hose.

11. (amended) A catheter assembly according to claim 5, wherein at least one protrusion defines a resilient vane adapted to contact an outer surface of the catheter.

12. (amended) A catheter assembly according to claim 1, wherein the sealing means comprises a ring shaped member arranged between an inner surface of the hose and an outer surface of the catheter.

14. (amended) A catheter assembly according to claim 12, wherein the ring shaped member is adapted to co-operate with an inwardly extending protrusion of the inner surface of the hose.

15. (amended) A catheter assembly according to claim 12, wherein the ring shaped member is adapted to co-operate with an outwardly extending protrusion of the catheter.

16. (amended) A catheter assembly according to claim 1, wherein the distance from the proximal end of the catheter package to the position of the sealing means constitutes between 0 and 100 % of the total distance between the proximal end of the catheter package and the opposite distal end of the package, such as 0%, such as 10%, such as 20%, such as 30%, such as 40%, such as 50%, such as 60%, such as 70%, such as 80%, such as 90% or such as 99%.

17. (amended) A catheter assembly according to claim 1, wherein the sealing means is adapted to provide a substantially liquid tight seal between the catheter package and the catheter, while a first length of the catheter is being dismantled over a first dismantle period.

18. (amended) A catheter assembly according to claim 1, wherein a liquid flow channel is defined between the catheter package and the catheter while the catheter is being dismantled over a second dismantle period.

19. (amended) A catheter assembly according to claim 17, wherein the length of the first dismantle period constitutes between 0 and 100 % of a total length of the package, such as 0%, such as 10%, such as 20%, such as 30%, such as 40%, such as 50%, such as 60%, such as 70%, such as 80%, such as 90% or such as 100%.

20. (amended) A catheter assembly according to claim 17, wherein the substantially liquid tight seal is provided continuously between the catheter package and the catheter over the first dismantle period.

21. (amended) A catheter assembly according to claim 1, wherein the catheter is provided with an outer surface part which, when treated with a friction-reducing substance, exhibits a low friction surface character.

23. (amended) A catheter assembly according to claim 21, further comprising an amount of the substance sufficient for effecting a treatment of at least the proximal end of the catheter, so as to provide a low friction surface property of at least that part of the catheter surface.

26. (amended) A catheter assembly according to claim 23, wherein the substance is a lubricant.

27. (amended) A catheter assembly according to claim 23, wherein the substance is a water based solution for treatment of a hydrophilic catheter.

28. (amended) A urinary catheter according to claim 1, wherein the package is provided with an opening for draining a liquid substance out of the package, said opening being closed by closing means connected to said catheter for causing opening of the package upon removal of the catheter from the package.

30. (amended) A catheter assembly according to claim 28, wherein the opening is being closed by a distal end of the catheter itself.

31. (amended) A catheter assembly according to claim 1, wherein the package is formed with a wall of a substantially gas impermeable material so as to allow long time preservation of the catheter and a liquid substance in the package.

32. (amended) A catheter assembly according to claim 28, wherein the closing means connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing means in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package.

34. (amended) A urinary catheter assembly according to claim 32, wherein the flow channel of the closing means further comprises at least one inlet allowing a liquid substance to flow between the one of either the lower or upper receptacles and the conduit of the catheter.

37. (amended) A catheter assembly according to claim 1, wherein the hose is formed with a wall of a flexible material so as to allow the hose wall to be squeezed into contact with the catheter by finger pressure for use as an applicator for guided non-contaminating insertion of the catheter.

38. (amended) A catheter assembly according to claim 1, wherein the hose is provided with a variable length, allowing the hose to be contracted for exposing the proximal end of the catheter through

the catheter outlet.

40. (amended) A catheter according to claim 38, wherein the variable length is provided by a concertina folded wall part of the hose.

41. (amended) A catheter assembly according to claim 1, wherein package is being closed in the proximal end by a detachable closure.

42. (amended) A urinary catheter assembly according to claim 1, wherein the catheter package further comprises a compartment being closed in a first end whereas in a second opposite end it is detachably connected with said hose, the compartment being formed with a wall of a flexible material so as to allow the compartment wall to be squeezed into contact with the catheter by finger pressure for use as an applicator for guided non-contaminating insertion of the catheter into the urinary canal after opening the first closed end and detachment of the compartment from the hose.

44. (amended) A catheter assembly according to claim 42 [any of claims 42-43], wherein a detachable cover member is closing the first end of the compartment.

46. (amended) A catheter assembly according to claim 42, wherein the compartment is provided with a gripping zone for easing the grip during use of the compartment for insertion of the catheter into the urinary canal.

47. (amended) A catheter assembly according to claim 44, wherein the cover member is provided with a gripping zone for easing the grip during detachment of the cover member.

48. (amended) A catheter according to claim 1, wherein the hose is provided with a gripping zone for easing the grip during insertion of the catheter into the urinary canal.

49. (amended) A catheter assembly according to claim 46, wherein the gripping zones are substantially radially extending.

50. (amended) A catheter assembly according to claim 42, wherein the connection between the compartment and the hose is provided by a weakening line for tearing off the compartment from the hose.

52. (amended) A catheter assembly according to claim 42, wherein the compartment is provided with a weakening line for opening the first end by tearing off a first end part of the compartment.

53. (amended) A urinary catheter assembly according to claim 1, wherein the distal end of the package is connected with a reservoir for accommodation of a liquid substance.

55. (amended) A catheter assembly according to claim 53, wherein the connection between the distal end of the package and the reservoir is adapted to allow the liquid substance to flow in a direction from the package to the reservoir and to prevent the liquid substance to flow in a direction from the reservoir to the package.

56. (amended) A catheter assembly according to claim 53, wherein the reservoir defines a draining spout for draining the liquid substance out of the reservoir.

59. A catheter according to claim 57, wherein the detachable cover member is connected to the spout via a tear-off line.

62. (amended) A catheter assembly according to claim 60, wherein the catheter is provided with an outer surface part which, when treated with a friction-reducing substance, exhibits a low friction surface character.

67. (amended) A catheter assembly according to claim 64, wherein the substance is a lubricant.

68. (amended) A catheter assembly according to claim 64, wherein the substance is a water or saline solution for treatment of a hydrophilic catheter.

69. (amended) A catheter assembly according to claim 60, wherein the package is formed with a wall of a substantially gas impermeable material so as to allow long time preservation of the catheter and the substance in the package.

70. (amended) A catheter assembly according to claim 60, wherein the closing means connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing means in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package.

72. (amended) A urinary catheter assembly according to claim 70, wherein the flow channel of the closing means further comprises at least one inlet allowing a liquid substance to flow from the receptacle to the conduit of the catheter.

76. (amended) A catheter according to claim 74, wherein the variable length is provided by a concertina folded wall part of the hose.

77. (amended) A catheter assembly according to claim 74, wherein package is being closed in the proximal end by a detachable cover.

79. (amended) A catheter according to claim 74, wherein the hose is formed with a wall of a flexible material so as to allow the hose wall to be squeezed into contact with the catheter.

REMARKS

The foregoing Preliminary Amendment is requested in order to delete the multiple dependent claims and avoid paying the multiple dependent claims fee.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Early action on the merits is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

3. (amended) A catheter assembly according to claim 1 [or 2], wherein the sealing means is arranged between an outer surface of the urinary catheter and an inner surface of the hose, the cavity thereby defining an upper receptacle located near the proximal end of the package and an oppositely located lower receptacle between the catheter and the hose (for a friction reducing substance).

4. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the sealing means comprises a radially outwardly extending protrusion of the outer surface of the catheter.

5. (amended) A catheter assembly according to claim 1 [any of claims 1-3], wherein the sealing means comprises at least two radially outwardly extending protrusions of the outer surface of the catheter.

7. (amended) A catheter assembly according to claim 4 [any of claims 4-6], wherein at least one protrusion defines a resilient vane adapted to contact an inner surface of the hose.

8. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the sealing means comprises at least one radially inwardly extending protrusion of the inner surface of the hose.

9. (amended) A catheter assembly according to claim 1 [any of claims 1-7], wherein the sealing means comprises at least two radially inwardly extending protrusions of an inner surface of the hose.

11. (amended) A catheter assembly according to claim 5 [or 6], wherein at least one protrusion defines a resilient vane adapted to contact an outer surface of the catheter.

12. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the sealing means comprises a ring shaped member arranged between an inner surface of the hose and an outer surface of the catheter.

14. (amended) A catheter assembly according to claim 12 [any of claims 12-13], wherein the ring shaped member is adapted to co-operate with an inwardly extending protrusion of the inner surface of the hose.

15. (amended) A catheter assembly according to claim 12 [any of claim 12-14], wherein the ring shaped member is adapted to co-operate with an outwardly extending protrusion of the catheter.

16. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the distance from the proximal end of the catheter package to the position of the sealing means constitutes between 0 and 100 % of the total distance between the proximal end of the catheter package and the opposite distal end of the package, such as 0%, such as 10%, such as 20%, such as 30%, such as 40%, such as 50%, such as 60%, such as 70%, such as 80%, such as 90% or such as 99%.

17. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the sealing means is adapted to provide a substantially liquid tight seal between the catheter package and the catheter, while a first length of the catheter is being dismantled over a first dismantle period.

18. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein a liquid flow channel is defined between the catheter package and the catheter while the catheter is being dismantled over a second dismantle period.

19. (amended) A catheter assembly according to claim 17 [any of claims 17-18], wherein the length of the first dismantle period constitutes between 0 and 100 % of a total length of the package, such as 0%, such as 10%, such as 20%, such as 30%, such as 40%, such as 50%, such as 60%, such as 70%, such as 80%, such as 90% or such as 100%.

20. (amended) A catheter assembly according to claim 17 [any of claims 17-19], wherein the substantially liquid tight seal is provided continuously between the catheter package and the catheter over the first dismantle period.

21. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the catheter is provided with an outer surface part which, when treated with a friction-reducing substance, exhibits a low friction surface character.

23. (amended) A catheter assembly according to claim 21 [any of claims 21-22], further comprising an amount of the substance sufficient for effecting a treatment of at least the proximal end of the catheter, so as to provide a low friction surface property

of at least that part of the catheter surface.

26. (amended) A catheter assembly according to claim 23 [any of claims 23-25], wherein the substance is a lubricant.

27. (amended) A catheter assembly according to claim 23 [any of claims 23-25], wherein the substance is a water based solution for treatment of a hydrophilic catheter.

28. (amended) A urinary catheter according to claim 1 [any of the preceding claims], wherein the package is provided with an opening for draining a liquid substance out of the package, said opening being closed by closing means connected to said catheter for causing opening of the package upon removal of the catheter from the package.

30. (amended) A catheter assembly according to claim 28 [any of claims 28-29], wherein the opening is being closed by a distal end of the catheter itself.

31. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the package is formed with a wall of a substantially gas impermeable material so as to allow long time preservation of the catheter and a liquid substance in the package.

32. (amended) A catheter assembly according to claim 28 [any of claims 28-31], wherein the closing means connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing means in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package.

34. (amended) A urinary catheter assembly according to claim 32 [claims 32-33], wherein the flow channel of the closing means further comprises at least one inlet allowing a liquid substance to flow between the one of either the lower or upper receptacles and the conduit of the catheter.

37. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the hose is formed with a wall of a flexible material so as to allow the hose wall to be squeezed into contact with the catheter by finger pressure for use as an applicator for guided non-contaminating insertion of the catheter.

38. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein the hose is provided with a variable length, allowing the hose to be contracted for exposing the proximal end of the catheter through the catheter outlet.

40. (amended) A catheter according to claim 38 [any of claims 38-39], wherein the variable length is provided by a concertina folded wall part of the hose.

41. (amended) A catheter assembly according to claim 1 [any of the preceding claims], wherein package is being closed in the proximal end by a detachable closure.

42. (amended) A urinary catheter assembly according to claim 1 [any of the preceding claims], wherein the catheter package further comprises a compartment being closed in a first end whereas in a second opposite end it is detachably connected with said hose, the compartment being formed with a wall of a flexible material so as to allow the compartment wall to be squeezed into contact with the

catheter by finger pressure for use as an applicator for guided non-contaminating insertion of the catheter into the urinary canal after opening the first closed end and detachment of the compartment from the hose.

44. (amended) A catheter assembly according to claim 42 [any of claims 42-43], wherein a detachable cover member is closing the first end of the compartment.

46. (amended) A catheter assembly according to claim 42 [any of claims 42-45], wherein the compartment is provided with a gripping zone for easing the grip during use of the compartment for insertion of the catheter into the urinary canal.

47. (amended) A catheter assembly according to claim 44 [any of claims 44-46], wherein the cover member is provided with a gripping zone for easing the grip during detachment of the cover member.

48. (amended) A catheter according to claim 1 [any of the preceding claims], wherein the hose is provided with a gripping zone for easing the grip during insertion of the catheter into the urinary canal.

49. (amended) A catheter assembly according to claim 46 [any of claims 46-48], wherein the gripping zones are substantially radially extending.

50. (amended) A catheter assembly according to claim 42 [any of claims 42-49], wherein the connection between the compartment and the hose is provided by a weakening line for tearing off the compartment from the hose.

52. (amended) A catheter assembly according to claim 42 [any of claims 42-51], wherein the compartment is provided with a weakening line for opening the first end by tearing off a first end part of the compartment.

53. (amended) A urinary catheter assembly according to claim 1 [any of the preceding claims], wherein the distal end of the package is connected with a reservoir for accommodation of a liquid substance.

55. (amended) A catheter assembly according to claim 53 [any of claims 53-54], wherein the connection between the distal end of the package and the reservoir is adapted to allow the liquid substance to flow in a direction from the package to the reservoir and to prevent the liquid substance to flow in a direction from the reservoir to the package.

56. (amended) A catheter assembly according to claim 53 [any of claims 53-55], wherein the reservoir defines a draining spout for draining the liquid substance out of the reservoir.

59. A catheter according to claim 57 [any of claims 57-58], wherein the detachable cover member is connected to the spout via a tear-off line.

62. (amended) A catheter assembly according to claim 60 [any claims 60-61], wherein the catheter is provided with an outer surface part which, when treated with a friction-reducing substance, exhibits a low friction surface character.

67. (amended) A catheter assembly according to claim 64 [any of claims 64-66], wherein the substance is a lubricant.

68. (amended) A catheter assembly according to claim 64 [any of claims 64-66], wherein the substance is a water or saline solution for treatment of a hydrophilic catheter.

69. (amended) A catheter assembly according to claim 60 [any of claims 60-68], wherein the package is formed with a wall of a substantially gas impermeable material so as to allow long time preservation of the catheter and the substance in the package.

70. (amended) A catheter assembly according to claim 60 [any of claims 60-69], wherein the closing means connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing means in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package.

72. (amended) A urinary catheter assembly according to claim 70 [claims 70-71], wherein the flow channel of the closing means further comprises at least one inlet allowing a liquid substance to flow from the receptacle to the conduit of the catheter.

76. (amended) A catheter according to claim 74 [any of claims 74-75], wherein the variable length is provided by a concertina folded wall part of the hose.

77. (amended) A catheter assembly according to claim 74 [any of claims 74-76], wherein package is being closed in the proximal end by a detachable cover.

79. (amended) A catheter according to claim 74 [any of claims 74-78], wherein the hose is formed with a wall of a flexible material

so as to allow the hose wall to be squeezed into contact with the catheter.